Episode 72. Latinx clinical research inclusion: how Dr Fabian Sandoval and Dr Gustavo Corrales teamed up to move the needle.

Posted on November 11, 2020.

Bringing clinical research to Latinx communities has become a joint mission for today's podcast guests, Dr Fabian Sandoval and Dr Gustavo Corrales. New FDA mandates require clinical trial participants to accurately reflect the population, so researchers are working harder than ever to ensure race, ethnicity and gender inclusion. But with so many moving parts, this is hard to achieve. Hosted by Dr. Minerva Campos, our guests discuss why participation is so important, where the process breaks down, and solutions to move the needle.

Dr. Campos: Welcome to the Healthcare Disparities Podcast brought to you by the Movement Is Life Caucus. This podcast brings you conversations about health disparities with the people who are working to eliminate them. Hi, I'm Dr. Minnie Campos and represent the National Hispanic Medical Association on the Movement Is Life Caucus. These two organizations have joined in a collaborative effort to eliminate the health and healthcare disparities that exist in our country today in order that we may truly achieve equity in health and healthcare. Today, we are very pleased to discuss the state of diversity, inclusion and equity in clinical trials with Dr. Fabian Sandoval, MD, CEO and Research Director of the Emerson Clinical Research Institute in Washington DC, and Dr. Gustavo Corrales, MD, an ophthalmologist specialist trained in cornea and cataract surgery who is principle with Vision Consultants & Surgeons in Falls Church, Virginia. Thank you both Dr. Sandoval and Dr. Corrales for joining us today to talk about how you have brought clinical research to the Latinx communities of the Washington DC Metro Area.

I want to give a little bit of backdrop as to why we're discussing this today, and I think it's important to remember that research is going on all over the world, but we have

had issues with diversity in the population that is involved in clinical research. You know, this country has had a longstanding problem with social and health inequities. The COVID-19 pandemic has certainly brought this fact to light and we're just beginning to understand how the harsh and unjust impact that structural and systemic racism has had on our society. We know that COVID-19 has disproportionately infected and lead to increased morbidity and mortality among the Latinx and African American communities, when compared to the white population of this country. So, understandably, we're turned to the development of effective and safe vaccines and medicines and I really emphasize safe and effective because it is well-known that there has been a lack of diverse representation of people of color in clinical trials including those from Latinx and African American communities, potentially creating issues of safety and efficacy of new vaccines and treatment for populations, which have already shown that they are at the highest risk of infection. Dr. Sandoval, I'm going to start with you. You're no stranger to research or advocacy for the Latinx community. You have over 25 years of bench to bedside research experience in your diversified research career including NIH. You're also very much involved in the community and have an Emmy award winning channel every week called, "Tu Salud, Tu Familia," "Your Family, Your Health". You are someone that's especially interesting to talk to about this. Tell us about the Emerson Clinical Institute. What brought you to this particular work?

Dr. Sandoval: So, thank you, Dr. Campos. So, what happened was in my career and research, I started to notice a little bit of lack of my own people participating in studies and I noticed that because when I was working at a major hospital in Virginia, I told all the departments, even though the hospital does have interpreters, if you need an interpreter to help you with recruiting a patient, talking and helping enroll a patient into a study looking through the consent form that's in Spanish, call me. Please call

me because I will help you and I asked them to give me a copy of all of their consents that were Spanish consents for their studies, so that I would have them ready. Minnie, it was eight months, and no one ever called me until one of the nurses said, “Why do you have this stack of consent forms?” I said, “Well, just in case someone calls,” and it struck me. It’s like no Hispanic patients participating in the studies. What’s going on? And, at that point I was also representing the hospital for the Society for Clinical Research Sites at the Society for Clinical Research Sites and I went to a conference and I realized that we could actually start our own research institute in a different manner. So, I started the idea and moved into the starting of Emerson Clinical Research Institute and I did it, not really knowing where I was going, not really, realizing that diversity was an issue. I did it just because I wanted to help my own community out and then realized, at that point, once I got started in a neighborhood in northeast DC, that African Americans were also having the same disparity issue and it started to grow from there and that’s how I got started, and by a serendipitous chance someone told me, “You should go talk to Dr. Corrales. He would probably want to help out the community because he’s the only ophthalmologist in the area who is Spanish speaking and is a surgeon.” I met Dr. Corrales. He didn’t know I was just a one-man show because I presented myself as bigger than that and Gustavo saw the idea and believed in what we were doing and really, took a chance on becoming one of our investigators and it’s been six years since we’ve had this partnership and it’s a great relationship.

Dr. Campos: Dr. Corrales, you also have had a lot of history in not only research, but in your community, in this community. You took your residency in ophthalmology at the Eye & Ear Institute at the University of Pittsburgh Medical Center and then followed that with a fellowship in cornea and complex cataract surgery at the prestigious New York Eye & Ear Infirmary. You are Board Certified and a Fellow with the American

Academy of Ophthalmology and you're also very committed to the advancement of the field of ophthalmology through your work in clinical research and your commitment to serving the Latinx community. What has motivated and inspired you to involve yourself in clinical research at the practice level?

Dr. Corrales: Clinical research and research, in general, has always been an interest since I was a resident, even before medical training. It's just, I think, it's part of the basic curiosity that we all have, and everybody chooses to explore, you know, to develop this curiosity in different ways. Some people might want to become a biologist, other people want to explore the mathematical aspect and are curious about that and they become engineers or, you know, or computer scientists. I think mine has always been toward the life sciences and biology. So, I decided to explore medicine. I had a lot of questions, and then, ophthalmology. So, throughout residency, we always were involved in research, and then, when I came out of university setting and did come out into the community, there's no research. There's no access to research, just because it is really, bound by needing a lot of resources and if you want to do basic research you need a lab. Well, that requires a lot of resources. If you want to do clinical research, well, where are they? What do you need in order to make this research happen? So, there are a lot of things that need to happen at the same time. You have to have the, first of all, know what research is available. You have to know where to look, who the sponsors are. You have to contact them. You have to have a research coordinator. You have to do a lot of paperwork. So, there are just so many barriers to clinical research out in the community that luckily when I met Fabian and he was starting his company, his research company of his own, and I was starting my clinic on my own. So, we were like, "Oh, I'm interested in what you are doing." "Well, I'm interested in what you are doing, too." So, let's join forces and slowly we've just been developing and adapting to our community and also bringing the sponsors

on, the sponsors of the clinical trials. I remember, in the beginning, it was so hard to get a consent in Spanish. A lot of the marketing material, a lot of the informational material was not in Spanish and we had to work with them to get them to translate in Spanish. So, you know, as time has gone by, the years have gone by, and we get more clinical research, I see that, from the beginning, a lot of sponsors are just including Spanish, Spanish consent. So, there's definitely been a change, which I think Fabian has been doing great work at that because he's always conference calls with the sponsors and making sure that we get all the right resources to include minority, well, what we call minority, right, but it's not really. In our clinic, in our practice, it's, actually, the majority.

Dr. Campos: The majority, right. So, the two of you actually have been the ones knocking on the doors of the sponsors, not the other way around. Not the sponsors knocking on your door, "Oh, please take this study." You know, "We're looking for Latino participants to enroll." So, you're the ones that have gone in and said, "Look what we have to offer you and actually, in a way, made them understand that there are ways to get Latino and, probably, as well, the African American, Fabian, to join these studies. Is that about, right?

Dr. Sandoval: I think it's been both ways. I know that several companies have actually created diversity departments within their research sections. So, yes, I think it's been both ways and thankfully, it's getting better. It's getting better.

Dr. Campos: So, Dr. Sandoval, are there sound scientific arguments for diversity and inclusion in scientific trials and what are they?

Dr. Sandoval: So, the biggest one is to make sure we know it's going to work on diverse communities, once the medication is actually approved. That is the biggest scientific reasoning for doing it. Our populations as we say are mixing. We have a lot of different races marrying, now, and it's just getting more and more complex and our genetic pool changes so much that if we are not on top of this, it's not going to work effectively and there's evidence for this. There's a drug for a cardiac condition that does not work very well in Caucasians but works excellent in African Americans, and they would not have known this if it wasn't for a research study. So, fortunately, now, we're able to prescribe better medications for individuals and have, at some point, this personalized medicine is supposed to happen. It's going to be a while before true personalized medicine happens, but having the ability to have all communities participate in it, we will know what side effects are more evident in our communities that there are in others, and that's very important.

Dr. Corrales: Yes, I mean, there is definitely a big genetic component. If you think about it, if you go back to the basics, everything that we consume has an effect on the body, from the food that we consume, some food can lead to diabetes and hypertension, other foods can lead to actually you having a healthy body. So, just from the simplest things that we consume to the medications that we take has a biological effect on the body, and everybody's biology tends to be different, just by genetic conditions. So, if we go back to the basics, it becomes that we are all different because we're all genetically different at some level. So, any drug, any medication, any action that we take, you can take the simplest thing like smoking. Some people develop cancer from smoking, other people smoke all their life, and they die of old age. So, there's definitely a genetic variant that might be genetic, might be environmental, but, definitely, everybody reacts in a different way to the same stimulus, and this may be a pharmaceutical, it might be a food, it might be a cigarette, it might be whatever it is,

but we all react different. So, there's, definitely, a lot to discover about personalizing medicine, by race, by person, by where you live, by, you know, a genetic predisposition, a genetic map of your body. So, I agree 100%. We have a lot to do and the only way to find out, in the general, with our technology, with our current technology, is to really, do clinical trials. In the future we might have a genetic composition of this preparation versus this preparation and letting a computer grab the drug and taste it and test it against that genetic composition in a computer and in five minutes do 20 years…

Dr. Campos: Of clinical research.

Dr. Corrales: Clinical research, right, exactly. With the technology that we have, right now, clinical trials that include different people is real, important.

Dr. Campos: We talked a little bit about this earlier, Dr. Corrales, but what are the barriers that exist within the Latinx communities, within your own patients, as it pertains to participation in clinical trials.

Dr. Corrales: Well, if we're going to go to specifics, the biggest barriers would be one language, and that's why I think we had a lot of success recruiting patients that are different, that are called diverse. Just because everybody in Fabian's office and Dr. Sandoval's office and my office, everybody's bilingual. We cannot hire people that don't speak both languages. So, if somebody comes in speaking Spanish or English, they feel perfectly comfortable. So, I think that's been something that has helped through this recruitment. So, the first part is, obviously, language. If you cannot communicate, you cannot build trust and that's, again, going back to the basic label, even with a pet you have to be able to have some type of communication, and then, you build trust and

it's no different from us people. Over time, you build the trust, and we build the true communication. So, that's the first barrier. Then, that brings us to the second one, which is the trust. A lot of people that may not trust the healthcare system for example or they may not know the healthcare system. They will not know if they don't have their legal documents for example to be in the country, you're not going to rat them out. You're not going to call immigration services. So, you break those barriers by building trust, and you build trust by communicating. So, I think that once you can break through that communication barrier in your own language, then, all those other barriers become smaller and smaller.

Dr. Campos: You, Dr. Sandoval, what barriers have you seen from not only patients but providers to involve themselves in research? What kinds of things get in the way there?

Dr. Sandoval: You know what? Before I answer that, it's so good to hear Dr. Corrales give that answer because I kind of say that same thing all the time, but I've never really asked him that exact same question. So, he sees regular practice plus research patients and he has the same statement that I do when I see, and I'm seeing research patients all day long, and it's the trust and it's that language barrier. So, it's great that we are on the exact same wavelength. So, the other barriers that I see for providers is back to Dr. Corrales, it's how are they going to find a place? How are they going to have research? Because I know if I were to probably ask Dr. Corrales, right now, "Hey, would you want to be a PI in one of my studies?" He would probably say, "No way. I've got no time," because he's got this gigantic, busy practice and he would have not thought twice. So, I was lucky, thank God, to get Dr. Corrales in the right moment because he had the time to do it and that is probably the biggest barrier is having the time, making the time. Providers don't do this because, you know, providers should not try to do this to try and get rich. They do this because they have

the altruistic belief, like Dr. Corrales does, that there is a greater good in conducting science. He is a scientist at heart and that's what's so important is finding those scientists that have the time, that want to make the time, and want to do more with their regular careers. So, that is the biggest barrier, making time, because if you go to an institution, a large medical institution, unless they are a university setting, they're going to have the exact same problem. We don't have time. We need to have RVU's. The hospital is making us go, go, go, go, and if we're not generating RVU's, we're not going to be allowed to do any regular work. If you want to do research, it has to be on your own time, and that's what providers are told at hospital settings, and that's what's killing the research side of any provider that wants to conduct studies as they grow into their career. I can't harp on it enough is having them to work and then having a mentor, having a mentor that's going to hold their hand and say this is how you conduct research. This is the team that you need and that's what we do. We make sure we mold providers into scientists and let them see the value and let them complain about all the paperwork that has to get done, so that we're there to make it happen. So, those are the barriers to providers, finding the providers, and then, having that love connection between the sponsors and the sites. Where are we going to get that person that is going to say, "There's a site. There's the pharma company. Let's make it happen." Because pharma companies are trying to find sites and we're trying to find the pharma companies and we're all waving these individual flags and it's super hard to find each other until we're an established organization like we are.

Dr. Campos: That's really interesting. Do you think, then, that the scientific community has done enough to diversify their studies? Are they working hard enough to do it?

Dr. Sandoval: I think the sponsors are trying, yes. I think the pharma companies are trying to make a difference, but it's important for pharma companies to do more than just say we have a diversity officer. We have a chief diversity whatever in the company. We're doing a project with someone whose whole focus says, "We are doing this project for diversity in clinical trials." You guys, they sent us the brochures, in English. The whole mission is diversity that's why they reached out to me. So, they have good intent.

Dr. Campos: They have a lot to learn. They have a lot to learn you can see that.

Dr. Sandoval: This is no small company, you know, it's important. Their minds and hearts are in the right places. It's just continuing the execution. I will say we've gone a long way from where we were probably 15 years ago, when diversity was an issue then, but I think, now, it's becoming a better reality. We are moving this needle forward for sure, now, because ten, fifteen years ago, there weren't diversity chiefs, people in charge of diversity as part of their titles in these large companies. So, yes, it's happening. Now, the reality, next is what is the carrot and what is the stick. It doesn't matter. We will get paid the exact same amount of money if we enrolled a Caucasian, Hispanic and African American patient. It doesn't matter. We all get the same thing. Dr. Corrales will get reimbursed the same. I'll get paid the same. So, there has to be something more. It's going to take tons of effort for there to be a legislative movement. So, FDASIA 907 exists. FDASIA is the FDA's Safety Innovations Act 907 that talks about the importance of diversity in clinical trials, but that's just this act from FDA. Unless, there's a real move from Congress to say there has to be a law, we just will kind of go along, you know, unless there's something else called the FDA Snapshot website that you can go on there and you can see the last drugs that were approved and you can see how many whites, how many Asians, Caucasians, Hispanics were in this

trial. So, it's kind of like what I call a little scarlet letter that the FDA just kind of posts for everyone to see. It's not the sponsors fault necessarily. It's just not the sites fault. It's just what it is. So, we need to move and continue to grow in the diversity movement of having more diverse sites.

Dr. Campos: Do you see benefits to your patients Dr. Corrales in enrolling them in these trials? Have you had a patient where you think, "Wow, if I hadn't done this, this might not have happened"?

Dr. Corrales: Yes, definitely. I've had patients who a lot of patients who could not afford the medications that the clinical trials provided. Patients that would not have had any treatment if they were not enrolled in the clinical trial. There are many barriers to that from transportation to family members, somebody's elderly and doesn't know the system, doesn't drive in United States. So, this is usually parents of people that came here and then they brought their parents. The parents, now, are in a tough position. They can't even walk outside. They can't go outside. They don't understand the language. They don't understand the system. So, then, they have a medical condition that requires relatively frequent follow-ups. So, the good thing about a clinical trial is that we can provide all this. We can provide transportation. We can provide compensation for coming to the office. We can provide the medication for free. And, we have to understand, people, when they say, "Oh, well, why are we doing all that? I don't want to be a guinea pig. I don't want to participate in the clinical trial." Right?

Dr. Campos: Right.

Dr. Corrales: Well, this is too good to be true. So, then, we have to go back to why we can do this and it is that the sponsor has a big interest in getting this through the FDA because once it gets approved, then, everybody can use it. They have the whole market, and the United States is the biggest, biggest pharmaceutical market in the whole world. Over 70% to 80% of the population is on some type of medication. It is just phenomenal. So, once we get it past the FDA, so, they're willing to pay for all these minor expenses. So, while all this is happening, and we can benefit the patients and provide them better access to those medications. The second thing that I want to mention is that these medications that we are in clinical trials, during the Phase 3 clinical trials, getting ready to be launched, what that means is they're already past the Phase 1 and Phase 2. So, these are medications that have already been tested, that they're safe, they're non-toxic, they're effective, and now, what we're really doing is seeing how trying to find the minor details in the general population to see how people really react to this, but, usually, we get the clinical trials Stage 3 in their second phase. There was another Stage 3 clinical trial that already happened. It can be somewhere else. It can be sometimes, very often, it's in another country, and then, they get that data, bring it to the FDA, now, they can do their clinical trials here. So, it is relatively safe that these medications are basically ready to go into the market. So, all the hard testing that's already proven this is not toxic, many times we take these medications that are already on the market, and the pharmaceutical companies, they want to repackage it for another indication and then, they need to do another clinical trial or they want to change the vehicle a little bit. For example, instead of an eyedrop, they want to do it as an implant. Alright, so, people don't have to use eyedrops and just releases the medication slowly. This is already a medication that has been approved. It's in the market, has been in the market. We've been using it for many years, but now, they want to repackage it and reformulate it. So, they need to do another clinical trial. So, this is a very safe medication that we already,

now, we've been testing it for over ten years in the real market. So, all our patients can benefit from participating in these types of clinical trials. The medications are relatively safe, and we can take advantage of all the resources that this provides.

Dr. Campos: Dr. Sandoval for you, what do you hear back from providers, what feedback do you get, those that have been involved with you on trials? Do they feel that it has benefited them?

Dr. Sandoval: Yes, it has. It's very gratifying for providers to know that they're offering their patients something new that can help them. It puts the provider at a different level of intellect when it comes to some of their colleagues because, now, the providers can speak to something that their colleagues has no idea is even out yet or can't speak as much about it or don't have the experience about it. So, professionally, it's very rewarding. That is probably the biggest part for the provider is kind of own self-esteem. We get bored doing the same thing over and over, again, and whatever kind of practice you're doing, this kind of throws a little bit of a little extra sauce on your day because it's not the same kind of patients. It's not the same technique. It's a little bit different. I know, Dr. Corrales, we have to pull them and grab them, as soon as he can to put them on his schedule, so that we can put them on there because it's something different and exciting. I love that. I, personally, love it because I'm always learning. I did the ophthalmology stuff when I was in med school, but the stuff that I've learned from Gustavo is beyond anything that I ever thought. I did OB/GYN, and I remember OB/GYN, but the stuff that we're doing on the GYN side is great, mental health same thing. So, I get to touch a little bit of everything, stuff that I wouldn't otherwise have done and would have been bored and I know the providers are getting the same thing. Then, when some medication comes to market that's even better because now, they're really excited that I was the one that helped get something on the

market, and we've had several of those. Now, some providers do get scared. Some providers do hear the word FDA and run. Some people hear, you're going to get an audit, and they just are panicked but that's kind of the area that we have a good hold on that we can say that it's not a bad thing. It's okay. We have everything taken care of. We do have legal. There's legal and all the other stuff that's associated with it. We make sure everything is done properly. Let me tell you, in five years, I don't know if Dr. Corrales realizes this, but he has done 15 studies in five years. He's been either a PI or a sub-PI on 15 studies. That's great.

Dr. Campos: Congratulations.

Dr. Sandoval: It's in the report.

Dr. Campos: Our organization, this Movement Is Life, is very interested in trying to do what it can with social justice and health equity and the concerns that we have about them and this is just a very broad question. You don't have to come out with a long, long answer but it's mostly just how you feel about it. Do you feel that the science community has an obligation to address social justice and health equity? You're addressing it, I think in the work that you're doing, right now, both you because that's social justice and health equity for the patients that you touch who might not have at all been involved were it not for you and the community. So, do you feel that the science community, as a whole, has a responsibility to address that in communities.

Dr. Sandoval: For sure. Of course, they do. One of the reasons, besides the fact that we are, I always say research is a complement to medicine. We are doing something in addition to what these providers are able to do, but this social justice that we see in healthcare, research has to play a role in it, and that's part of the diversity movement

because it's going to get expensive. If they don't want to look at it from the health perspective, they can look at it from the financial perspective into the community. It's much cheaper to take care of someone that just has diabetes, and we can treat them quickly, versus someone who now has a stroke because of diabetes. If we don't care for our patients in time, the wave of what's going to come is even worse. So, we have to step up. There has to be more Dr. Corrales' out there that does regular practice, and then, does research because without providers, without diverse providers, this wave is going to knock us out and it's not going to be pretty. We need to represent, and we need to have this movement take place.

Dr. Corrales: I agree that yes, definitely, but you should also address it without having to wear our scientific hat. We should address in general. I don't think we should put we should differentiate which hat we're wearing. If I'm wearing a clinician hat or a researcher hat or a father hat or just somebody going to the mall hat, I think it's in general, somebody going to vote or whatever, you know, involving politics. I think, as a society, one group of people, yes, we should definitely not fall into using prejudice to differentiate between different people. I mean, basically, what we're getting at, the root of the question is should we follow the prejudices established by society today, which are different from the day, from 50 years ago or even 10 years ago. So, it's going to be different, these prejudices are going to be different 50 years from now. So, we should always try to break away from these barriers, from these mental barriers. So, yes, I agree, 100% that we should not fall trap, whatever hat we're wearing, we should not fall trap of these mental barriers that we grew up with.

Dr. Campos: Well, I think you've made some great arguments for just the importance of diversity, inclusion, equity in clinical trials for our discussion. I thank you so much for joining us this afternoon and thank you, again. I also want to thank all our listeners. We would

love for you to follow us and just remember that all previous podcasts are available on the Movement Is Life website at www.movementislifecaucus.com. Thank you, again, and please join us, again.

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